

## REMARKS

The Examiner requested that Applicants submit a substitute 1449 form for the one that was submitted on January 31, 2000 because the class and subclass designations were not filled in. Applicants submit herewith a substitute 1449 form with the class and subclass information completed.

Claim 58 has been rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejection of Claim 58 is respectfully traversed. The strains set forth in Claim 58 have been deposited under the terms of the Budapest Treaty. All restrictions on the availability to the public of the materials so deposited have been irrevocably removed by virtue of issuance of U.S. Patent No. 5,130,242.

Claims 53-66 have been rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of Claims 53-66 is respectfully traversed. The Examiner has taken the position that the process step of extracting lipids from euryhaline microorganisms is unclear since it requires the extraction from the microorganisms and not the fermentation medium. The Examiner then contends that it is unclear as to

whether the product is being produced within the microorganisms or within the fermentation medium. As the Examiner noted, the claims clearly recite the process step of extracting lipids from the microorganisms. The claims do not recite extraction or any sort of recovery from the fermentation medium. Thus, Applicants submit that the claims are unambiguous that the lipids are in the microorganisms and are extracted therefrom.

The Examiner correctly points out that the recitation of "the microorganism" in the dependent claims lacks antecedent basis since the process requires more than one microorganism. Claims 54-58 have been amended to comply with the Examiner's suggestion to pluralize the term "microorganism". Additionally, Claims 59-66 have been amended to pluralize the terms "lipid", and, where appropriate, "acid".

Claims 53-56 and 59-66 have been rejected under 35 USC 112, first paragraph. The Examiner has taken the position that the specification, while being enabling for a euryhaline microorganism of the genus *Thraustochytrium*, *Schizochytrium* and mixtures thereof, does not reasonably provide enablement for any and all euryhaline microorganisms for use in the claimed method.

The rejection of Claims 53-56 and 59-66 is respectfully traversed. In the Preliminary Amendment that was originally filed with the present application, U.S. Patent No. 5,130,242 was incorporated by reference in its entirety. In the paragraph bridging pages 8 and 9 of the present application, a collection and

screening process is described. On page 9, lines 2-3 of the present application, it is stated that: "This process is described in detail in related U.S. Patent No. 5,130,242." The present application has now been amended to include the detailed description of this collection and screening process from U.S. Patent No. 5,130,242 (see the amendment to the specification set forth above). Additionally, a specific embodiment of a collection and screening technique is described in great detail in Example 1 on page 20 of the present application. The collection and screening process fully enables one skilled in the art to practice the full scope of the claimed invention and to obtain euryhaline microorganisms in addition to euryhaline microorganism of the genus *Thraustochytrium*, *Schizochytrium* and mixtures thereof. It is respectfully submitted that the specification sets forth a repeatable method by which such microorganisms are obtainable. The Examiner has not identified or put forth any rationale as to why the collection and screening method would not work to identify other suitable microorganisms. In the absence of such an explanation by the Examiner, the reasonable assertion by the Applicants that the collection and screening method enable the full scope of the invention should be accepted. Therefore, the specification enables one skilled in the art to which it pertains to carry out the process steps of the invention with other euryhaline microorganisms.

It is respectfully submitted that all of Claims 53-66 are in condition for allowance. It is further respectfully requested that

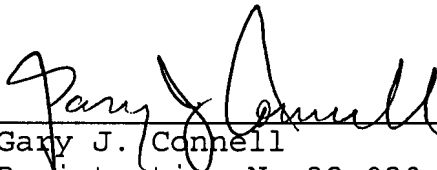
the Examiner withdraw the restriction requirement as suggested as a possibility by the Examiner in the latest Office Action. Because there are no prior art rejections outstanding, it is respectfully submitted that all of Claims 38-93 are in condition for allowance, and that the present case should be passed to issue with all Claims 38-93. In the event that the Examiner has any questions or concerns regarding the allowability of any claim, please consider this a provisional request for an Examiner's interview and please contact the undersigned attorney at 303-863-2973.

Attached hereto is a marked up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Marked-Up Version Showing Amendments."

It is not believed any fees are due, however, in the event any fees are due, please debit any underpayment to Deposit Account No. 19-1970.

Respectfully submitted,

SHERIDAN ROSS P.C.

By:   
Gary J. Connell  
Registration No. 32,020  
1560 Broadway  
Suite 1200  
Denver, Colorado 80202  
(303) 863-9700

Date: 9 July 2001

J:\2997\1\3\2\AMD1 Preliminary Amendment.wpd

B

Marked-Up Version Showing Amendments

IN THE CLAIMS:

Claims 54-66 have been amended as follows (unamended independent Claim 53 is reiterated below for the convenience of the Examiner)

53. (Reiterated) A process for producing lipids comprising:

(a) growing euryhaline microorganisms in a fermentation medium, wherein said euryhaline microorganisms are capable of producing about 1.08 grams per liter per day of long chain omega-3 fatty acids per 40 grams of sugar per liter at a sodium ion concentration of 60% seawater; and

(b) extracting lipids from said euryhaline microorganisms.

54. (Once Amended) The process of Claim 53, wherein said euryhaline microorganisms [has] have exponential growth rates of at least about 5 doublings per day at 25 °C.

55. (Once Amended) The process of Claim 53, wherein said euryhaline microorganisms [has] have exponential growth rates of at least about 7 doublings per day at 30 °C.

56. (Once Amended) The process of Claim 53, wherein said euryhaline microorganisms [is a] are microorganisms of the order Thraustochytriales.

57. (Once Amended) The process of Claim 56, wherein said euryhaline microorganisms [is] are selected from the group

consisting of *Thraustochytrium*, *Schizochytrium*, and mixtures thereof.

58. (Once Amended) The process of Claim 57, wherein said euryhaline microorganisms [is] are selected from the group consisting of ATCC 20888, ATCC 20889, ATCC 20890, ATCC 20891, ATCC 20892, and mixtures thereof.

59. (Once Amended) The process of Claim 53, wherein about 20% or less of the total fatty acids in said lipids [is] are omega-6 fatty acids.

60. (Once Amended) The process of Claim 53, wherein at least about 49% of the total fatty acids of said lipids [is] are omega-3 fatty acids.

61. (Once Amended) The process of Claim 53, wherein the ratio of DHA to EPA in said lipids is about 7.07 or less.

62. (Once Amended) The process of Claim 53, wherein at least about 64.5% of omega-3 fatty acids in said lipids is DHA.

63. (Once Amended) The process of Claim 53, wherein at least about 86% of omega-3 fatty acids in said lipids is DHA.

64. (Once Amended) The process of Claim 53, wherein the ratio of EPA to DHA in said lipids is from about 1:1 to about 1:30.

65. (Once Amended) The process of Claim 53, wherein the ratio of DPA to DHA in said lipids is at least about 1:12.

66. (Once Amended) The process of Claim 53, wherein the total fatty acid composition in said lipids comprises about 5% or less of C20:4w6 fatty acid.